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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,965	11/17/2000	Elizabeth M. Denholm	IT 106	7982

7590 09/24/2002

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EXAMINER

MELLER, MICHAEL V

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/24/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/715,965

Applicant(s)

DENHOLM ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2002 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/1/2002 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 19-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using chondroitinase AC and B from *Flavobacterium heparinum* in a method to decrease angiogenesis, does not reasonably provide enablement for any and all "glycosaminoglycan degrading enzymes" to decrease angiogenesis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

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The specification as filed, is enabled only for decreasing angiogenesis using chondroitinase AC and B from *Flavobacterium heparinum*, but is not enabled for any and all "glycosaminoglycan degrading enzymes" to decrease angiogenesis.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all "glycosaminoglycan degrading enzymes" to see if they decrease angiogenesis. Applicants themselves have argued in their previous response the criticality of the claimed chondroitinase AC from *Flavobacterium heparinum* to decrease angiogenesis.

Applicant has only shown in their examples chondroitinase AC and B from *Flavobacterium heparinum* used to decrease angiogenesis. With only knowing these two specific enzymes from two specific sources, it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given two particular enzymes from these two specific sources with which to decrease angiogenesis.

Thus, the claims are unduly broad and do not find proper support from the instant specification. Thus, the rejection is properly made.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2, 6-8, 19, 21, 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is confusing since it improperly claims a markush group. It starts out listing a group with one member, namely, bacterial glycosaminoglycan degrading enzyme and then lists specific enzymes both in singular and plural form. Further the markush group does not properly recite, "a, b, and c". Instead it recites, "a, b, and c, d, e, f". This is confusing. Further, what "recombinant nucleotide sequences in bacteria" is applicant referring to ? This is simply not understood. It is not clear from either the claims or the specification what the applicant is referring to.

Claim 6 is confusing since "the time" has no antecedent basis.

Claim 8 claims a confusing markush group since both general and specific diseases are contained in the same markush group.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Change to 103
Claims 1, 2, 6, 8-11, 20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sasisekharan et al.

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The invention is taught by this reference. A method for inhibiting angiogenesis is taught, see abstract, col. 1, col. 4, col. 5, col. 16-18.

Claims 1, 2, 4-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (of record).

Brown teaches treating the tumor of an individual with chondroitinase AC, of record. Since Brown teaches treating tumors this would include individuals with cancer and thus decreasing angiogenesis. When the enzyme is applied to the tumor it will inherently perform the claimed process.

Claims 1, 2, 4, 5, 9, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi (of record).

The reference is of record and teaches what is of record. On page 119, left column, it is clear that the enzyme inhibits tumor growth, *in vivo*.

Claims 1-5, 8-11, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/01648, see abstract, page 1, 8, 29-34, and the claims.

The reference teaches that heparinases and chondroitinases have been used to inhibit wound healing, thus decreasing angiogenesis.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeuchi, Sasisekharan et al., Brown, or WO 96/01648.

The references each teach one of the claimed enzymes used to treat a patient to decrease angiogenesis.

The specific amounts, types of enzymes, etc. are simply the choice of the artisan in an effort to optimize the results of the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller
Examiner
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MVM
September 20, 2002